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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,440	02/05/2004	Michal Daniely	26003	3178

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EXAMINER
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DUFFY, BRADLEY

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/771,440

Applicant(s)

DANIELY ET AL.

Examiner

Brad Duffy

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February, 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. This election/restriction requirement sets forth multiple elections applicable to the Inventions of Groups I-XXX (see item nos. 2-4 below).

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 2-5, 6, 7, 12, 13, 18, 20-23, 24, 25, 30, 31 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is an immunological stain and imaging the cells, classified in class 435, subclass 7.1.
  - II. Claims 2-5, 6, 8, 12, 14, 18, 20-23, 24, 26, 30, 31 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is an activity stain and imaging the cells, classified in class 435, subclass 7.2.
  - III. Claims 2-5, 6, 9, 18, 20-23, 24, 27 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is a cytogenetical stain and imaging the cells, classified in class 435, subclass 7.21.

- IV. Claims 2-5, 6, 10, 12, 18, 20-23, 24, 28, 30 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is an *in situ* hybridization stain and imaging the cells, classified in class 435, subclass 7.24.
- V. Claims 2-5, 6, 11, 12, 18, 20-23, 24, 29, 30 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is a DNA stain and imaging the cells, classified in class 435, subclass 6.
- VI. Claims 2-5, 7, 8, 13, 14, 18, 20-23, 25, 26, 31, 32 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is an immunological stain and one stain is an activity stain and imaging the cells, classified in class 436, subclass 542.
- VII. Claims 2-5, 7, 9, 15, 18, 20-23, 25, 27, 33 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is an immunological stain and one stain is a cytogenetical stain and imaging the cells, classified in class 436, subclass 540.
- VIII. Claims 2-5, 7, 10, 13, 18, 20-23, 25, 28, 31 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells

with at least two stains, wherein one stain is an immunological stain and one stain is an *in situ* hybridization stain and imaging the cells, classified in class 436, subclass 541.

- IX. Claims 2-5, 7, 11, 13, 18, 20-23, 25, 29, 31 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is an immunological stain and one stain is a DNA stain and imaging the cells, classified in class 435, subclass 7.9.
- X. Claims 2-5, 8, 9, 18, 20-23, 26, 27 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is an activity stain and one stain is a cytogenetical stain and imaging the cells, classified in class 435, subclass 7.7.
- XI. Claims 2-5, 8, 10, 14, 18, 20-23, 26, 28, 32 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is an activity stain and one stain is an *in situ* hybridization stain and imaging the cells, classified in class 435, subclass 7.71.
- XII. Claims 2-5, 8, 11, 14, 18, 20-23, 26, 29, 32 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is an activity stain and one stain

is a DNA stain and imaging the cells, classified in class 435, subclass 7.72.

- XIII. Claims 2-5, 9, 10, 15, 18, 20-23, 27, 28, 33 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is a cytogenetical stain and one stain is an *in situ* hybridization stain and imaging the cells, classified in class 435, subclass 7.6.
- XIV. Claims 2-5, 9, 11, 15, 18, 20-23, 27, 29, 33 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is a cytogenetical stain and one stain is a DNA stain and imaging the cells, classified in class 435, subclass 4.
- XV. Claims 2-5, 10, 11, 16, 17, 18, 20-23, 28, 29, 34, 35 and 36, drawn to a method of identifying cancerous cells or diagnosing cancer comprising staining cells with at least two stains, wherein one stain is an *in situ* hybridization stain and one stain is a DNA stain and imaging the cells, classified in class 435, subclass 7.9.
- XVI. Claims 38-41, 42, 43, 48, 49, 54, 56-58, 59, 60, 65, 66 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is an

immunological stain and imaging the cells, classified in class 435, subclass 7.91.

- XVII. Claims 38-41, 42, 44, 48, 50, 54, 56-58, 59, 61, 65, 67 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is an activity stain and imaging the cells, classified in class 436, subclass 64.
- XVIII. Claims 38-41, 42, 45, 54, 56-58, 59, 62 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is a cytogenetical stain and imaging the cells, classified in class 435, subclass 7.25.
- XIX. Claims 38-41, 42, 46, 48, 54, 56-58, 59, 63, 65 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is a morphological stain and one stain is an *in situ* hybridization stain and imaging the cells, classified in class 435, subclass 7.5.
- XX. Claims 38-41, 42, 47, 48, 54, 56-58, 59, 64, 65 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains,

wherein one stain is a morphological stain and one stain is a DNA stain and imaging the cells, classified in class 435, subclass 7.23.

- XXI. Claims 38-41, 43, 44, 49, 50, 54, 56-58, 60, 61, 66, 67 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is an immunological stain and one stain is an activity stain and imaging the cells, classified in class 435, subclass 7.92.
- XXII. Claims 38-41, 43, 45, 51, 54, 56-58, 60, 62, 68 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is an immunological stain and one stain is a cytogenetical stain and imaging the cells, classified in class 435, subclass 7.93.
- XXIII. Claims 38-41, 43, 46, 49, 54, 56-58, 60, 63, 66 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is an immunological stain and one stain is an *in situ* hybridization stain and imaging the cells, classified in class 435, subclass 7.94.
- XXIV. Claims 38-41, 43, 47, 49, 54, 56-58, 60, 64, 66 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains,



wherein one stain is an immunological stain and one stain is a DNA stain and imaging the cells, classified in class 435, subclass 7.95.

XXV. Claims 38-41, 44, 45, 54, 56-58, 61, 62 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is an activity stain and one stain is a cytogenetical stain and imaging the cells, classified in class 436, subclass 164.

XXVI. Claims 38-41, 44, 46, 50, 54, 56-58, 61, 63, 67 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is an activity stain and one stain is an *in situ* hybridization stain and imaging the cells, classified in class 436, subclass 165.

XXVII. Claims 38-41, 44, 47, 50, 54, 56-58, 61, 64, 67 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is an activity stain and one stain is a DNA stain and imaging the cells, classified in class 436, subclass 166.

XXVIII. Claims 38-41, 45, 46, 51, 54, 56-58, 62, 63, 68 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is a cytogenetical stain and one stain is an *in*

*situ* hybridization stain and imaging the cells, classified in class 436, subclass 170.

XXIX. Claims 38-41, 45, 47, 51, 54, 56-58, 62, 64, 68 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is a cytogenetical stain and one stain is a DNA stain and imaging the cells, classified in class 436, subclass 172.

XXX. Claims 38-41, 46, 47, 52, 53, 54, 56-58, 63, 64, 69, 70 and 71, drawn to a method of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample comprising staining cells with at least two stains, wherein one stain is an *in situ* hybridization stain and one stain is a DNA stain and imaging the cells, classified in class 436, subclass 811.

Claims 1 and 19 link inventions of Groups I-XV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1 and 19. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 37 and 55 links inventions of Groups XVI-XXX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 37 and 55. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C.

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121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. This application contains claims in Groups I-XV directed to a patentably distinct species: methods of methods of identifying cancerous cells or diagnosing cancer from biological samples selected from the cancers consisting of:

A. leukemia, B. lymphoma, C. brain cancer, D. cerebrospinal cancer, E. bladder cancer, F. prostate cancer, G. breast cancer, H. cervix cancer, I. uterus cancer, J. ovarian cancer, K. kidney cancer, L. esophagus cancer, M. lung cancer, N. colon cancer, O. pancreatic cancer, P. melanoma.

The species are independent or distinct because they differ in the method objectives. In the instant case, the cancers listed do not have a common origin, a method of identifying cancerous cells or diagnosing cancer for one would not necessarily work one for the other and the method objectives would be to identify cancerous cells or diagnose the specific cancer of the patient. Therefore, separate searches would be required to determine patentability for each method of identifying cancerous cells or diagnosing cancer, so restriction as required is proper.

If applicant elects any one of Groups I-XV, applicant is further required under 35 U.S.C. 121 to elect a single disclosed species in the above list from A-P for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consistent with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

4. Additionally, this application contains claims in Groups I-XV directed to a patentably distinct species: methods of identifying cancerous cells or diagnosing cancer from biological samples selected from the group consisting of:

- i. bone marrow cells, ii. lymph nodes cells, iii. peripheral blood, iv. cerebrospinal fluid, v. urine, vi. effusions, vii. fine needle aspirates, viii. peripheral blood scrapings, ix. paraffin embedded tissues, x. frozen sections.

The species are independent or distinct because they differ in the method objectives and reagents used. In the instant case, the biological samples listed do not have a common origin, a method of identifying cancerous cells or diagnosing cancer in one sample would not necessarily work one for the other and the method objectives would be to identify cancerous cells or diagnose the cancer that would be specific to the sample used. Therefore, separate searches would be required to determine patentability for each method of identifying cancerous cells or diagnosing cancer from biological samples, so restriction as required is proper.

If applicant elects any one of Groups I-XV, applicant is further required under 35 U.S.C. 121 to elect a single disclosed species in the above list from i-x in addition to one of A-P for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consistent with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

5. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions of Groups I-XXX differ in the method steps, parameters and reagents used. For example the methods of Groups I and XVI recite using both a morphological stain and an immunological stain, which are not required to be together in any of the other groups. Similarly, the other Groups, II and XVII, III and XVIII, etc. require a set of stains that are not required by any of the other groups.

Furthermore, the inventions of Groups I-XXX are directed to methods that recite structurally and functionally distinct elements and are not required one for the other.

For example, an immunological stain requires use of a specific polypeptide/antibody, which is not required by the other stains. Similarly, the other stains require the use of structurally and functionally distinct elements, which are not required by the other stains. Thus, the inventions of Groups I-XXX are directed to methods that recite structurally and functionally distinct elements, and are not required one for the other. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-XXX are separate in having different method steps, parameters and reagents used and are patentably distinct.

The methods of Inventions of Groups I-XV and Groups XVI-XXX differ in the method objectives and reagents used. The methods of Groups I-XV recite using a biological sample to identify cancer cells or diagnose cancer. The methods of Groups XVI-XXX recite using a urine sample to identify transitional cell carcinoma cells or diagnose bladder cancer, which is not required by Groups I-XV. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-XV and Groups XVI-XXX are separate in having different method objectives and reagents used and are patentably distinct.


6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classifications, restriction for examination purposes as indicated is proper.

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7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
Brad Duffy   
571-272-9935

David Blanchard  
Au 1643  
